REMARKS/ARGUMENTS

In the Office Action, objections were raised to the abstract (section 1), and to the description of Figures 7-9 and 16A (section 2a). Claim objections were raised to particular language in Sections 3a-d. Claims 3-28 and 30 were rejected on various grounds as allegedly indefinite in Sections 4a-g. Claims 1-3 were objected to as non-statutory subject matter in Section 5. Claims 1-28 and 30 were rejected as allegedly lacking enablement in Section 6. Claims 1-28 and 30 were rejected as allegedly lacking written description in Section 7. These objectioins and rejections are addressed in turn below.

The Objections to the Abstract and Specification

Objections were raised to the abstract (section 1), and to the description of Figures 7-9 and 16A (section 2a). The abstract and figure descriptions have been amended above to address the objections. No new matter is presented. Withdrawal of these objections is respectfully requested.

The Objections to the Claim Language

To address the objections under section 3, we have amended the claims as follows:

(i) there is no need to amend claim 6 to read "Toll-like Receptor 2 (TLR2)" in place of "TLR2", as that portion of the claims has been deleted.

(ii) there is no need to delete "for" from line 7 of claim 6 as that portion of the claims has been deleted.

(iii) In claim 10, we have replaced the word "comprising" with "comprises".

(iv) In claim 17, we have italicised the words E.coli and Bacillus subtilis.

The Indefiniteness Rejections

In order to address the objection under section 4 and 4a, claims 4, 5, 6, 7, 18, 20, 21 and 23 have been amended to revise the "and/or" terminology referred to by the examiner.

To address the objection under paragraph 4b, claim 3 has been amended to read "*The antibody of claim 1, wherein the antibody specifically binds through the [[its]] variable region[[s]] of the heavy chain comprising the amino acid sequence as depicted in SEQ ID NO:6 and the light chain comprising the amino acid sequence as depicted in SEQ ID NO: ~~6 and/or~~ 7, ~~or a variant thereof~~.*"

Additionally, the term "variable regions" has been clarified by amendment. Further, to address the objection under paragraph 4c, we have amended claim 5 so that it is dependent upon claim 3, rather than claim 1.

To overcome the objection under paragraph 4d., claim 6 has been amended to delete the term "or its complement".

To address the objection under paragraph 4e., claim 8 has been amended to replace the term "specifying" with the term "encoding".

To address the objections under paragraph 4f, claim 20 has been amended so that it assumes the recognised Markush group wording suggested by the examiner. Similar Markush group style wording has been introduced into claims 14, 15 and 21.

To address the objections raised under paragraph 4g, the term "agents blocking further pattern recognition receptors" has been amended to read "agents which block a pattern recognition receptor". Claim 21 has been amended to read "agents blocking a pattern recognition receptor selected from the group consisting of Toll-like Receptor 3 (TLR3), Toll-like Receptor 4 (TLR4), Toll-like Receptor 4 (TLR5), Toll-like Receptor 7 (TLR7), Toll-like Receptor 8 (TLR8) and Toll-like Receptor 9 (TLR9).

The Statutory Subject Matter Rejection

To address the objection under section 5, claims 1 to 3 now refer to an "isolated antibody".

Claim 1 has been further amended to introduce the term "antibody fragments". Basis for the inclusion of antibody fragments can be found in the description, as originally filed, at, at least page 5, paragraph 4 and page 6, paragraph 4.

Claim 1 has also been amended to define the structure of the light chain variable region and heavy chain variable region with regard to the amino acid sequence of their CDR (complementarity determining regions). Basis for defining the antibody with reference to the CDR sequences of the heavy and light chain variable regions can be found throughout the description as filed, and, at least, at page 9, paragraph 1 which states that "Italic/bold regions are CDR 1 to 3 defined by the IMGT database, both nucleic acid and amino acid sequences are marked accordingly (applies also to SEQ ID NO:2).

In particular, the CDR sequences of the heavy chain variable region can be clearly identified as the amino acid residues which are shown in both bold and italic typeface in SEQ ID NO:1 which is provided on pages 8 and 9 of the description as filed. Further, the CDR sequences of the light chain variable regions can be clearly identified as the amino acid residues which are shown in bold and italic typeface in SEQ ID NO:2 as found on page 10 of the application as filed.

Further support for the specific disclosure in the application as filed, of the CDR sequences of the heavy chain variable region recited in amended claim 1 can be found in the description at page 8, paragraphs 2 to 5 which state ".. the isolated nucleic acid of the invention comprises at least the sequence of nucleic acids No. 172 – 201, 244 – 294 and/or 385 – 417 of SEQ ID NO:1....", this text being followed by the explanation that "The above mentioned sequences comprise complementarity determining regions (CDR's) 1, 2 and 3, respectively". In turn the description also teaches at paragraph 3 of page 8 that "Regarding SEQ ID NO:1, more precisely, nucleic acids No. 172-195, 247-270 and 385-417 or parts thereof are preferred (CDR 1 – 3), which have been identified by application of the IMGT database". In terms of identifying the amino acid residues corresponding to the listed nucleic acids, these residues are shown in SEQ ID NO:1 in emboldened and italicised font, while the description further teaches that "A chart comprising SEQ ID NO:1 and its complementary sequence as well as the encoded amino

acids are depicted below. SEQ ID NO:1 is showing the nucleic acid and amino acid sequence of the heavy chain's variable region of the antibody of the invention".

Similar basis is provided for the identification of the CDR regions of the light chain variable region, with basis being found in the description at page 8, paragraphs 2 and 4 and further at page 9, paragraph 2. In particular, page 8, paragraph 2 reads "... the isolated nucleic acid of the invention comprises at least the sequence of ...nucleic acids No. 130 – 174, 220 – 240 and/or 337 – 363 of SEQ ID NO:2, or parts thereof". Page 8, paragraph 4 reads "Regarding SEQ ID NO:2, more precisely, nucleic acids No. 139-168, 220-228 and 337-363 or parts thereof are preferred (CDR 1 – 3), which were identified by the application of the IMGT database".

In terms of identifying the amino acid residues corresponding to the listed nucleic acids, these residues are shown in SEQ ID NO:2 in emboldened and italicised font, while the description at page 9, paragraph 2 further teaches that "A chart comprising SEQ ID NO:2 and its complementary sequence as well as the encoded amino acids are depicted below. SEQ ID NO:2 is showing the nucleic acid and amino acid sequence of the light chain's variable region of the antibody of the invention".

New claim 33 finds basis in the instant description at page 5, paragraph 4, and in particular the sentences "The term "antibody", is used herein for intact antibodies as well as antibody fragments, which have a certain ability to selectively bind to an epitope. Such fragments include, without limitations and as an example, Fab, F(ab')2, and Fv antibody fragment".

The Enablement Rejection

On pages 6 to 16 of the present office action, the examiner raises an enablement rejection on the grounds that there is allegedly not sufficient teaching in the instant specification to support the extension of the claims of the instant application to portions, variant and parts of antibodies, amino acids and nucleic acids. Without acceding to the correctness of these objections and solely in an effort to progress the prosecution of this application, references to variants and parts have been deleted from the amended claim set.

Applicant has introduced and/or retained references in the claims to antibody fragments. Applicant submits that there is sufficient basis in the application to show the manufacture of fragments of the antibody of the present invention. In that regard, examiner's attention is respectfully directed to Figure 16A and 16B of the instant specification as described at page 22 to 23 of the instant specification.

The Written Description Rejection

It is respectfully submitted that the amendments made to claim 1 render the objections raised by the examiner moot.

All the objections and rejections having been addressed above, withdrawal of same is respectfully requested. It is believed that no new matter has been added by this amendment, and Applicants respectfully request entry of same into the present application.

CONCLUSION

In light of the Amendments and Remarks herein, Applicant submits that the claims are in condition for allowance and respectfully request a notice to this effect.

Respectfully submitted,

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